

Notice of Allowability

Application No.

09/994,773

Examiner

Joyce Tung

Applicant(s)

HANYU ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to March 14, 2005.
2. ☒ The allowed claim(s) is/are claims 1-3, 6-15 and 18-24 (final claims 1-20).
3. ☒ The drawings filed on 11/28/2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

The Reasons for Allowance

The applicant's response filed March 14, 2005 to the Office action has been entered. Claims 1-3, 6-15, and 18-24 are pending.

1. The following is an examiner's statement of reasons for allowance:

Concerning claims 1-3, 6-15, and 18-24, no prior art has been found teaching or suggesting a method of stabilization of a physiologically active peptide in a process of preparing a powder containing the physiologically active peptide wherein the process comprises adding to an aqueous liquid at least one compound selected from the group of a nonionic organic, water soluble binder, and hydrogenated lecithin and wherein the nonionic organic, water soluble binder is selected from polyvinylpyrrolidone, a water-soluble, nonionic cellulose derivative defined in claims 6 and 18 and polyvinylalcohol.

The closest prior art is the reference of Bergstrand et al. (6,103,697, issued August 5, 2000). Bergstrand et al. disclose the preparation of pharmaceutical preparation containing a peptide (See column 12, lines 56-57). The active peptide may be admixed with mannitol, or cellulose derivatives or polyvinylpyrrolidone (See column 12, lines 56-67) and surfactants lecithin (see column 13, lines 53-55). A solution containing active peptide was dried by lyophilization (See example 34, column 9, lines 58-60). However, there is no teaching or suggestion that the surfactants or other additives are added to physiologically active peptide in aqueous solution, to stabilize a physiologically active peptide during drying and then dried to form a powder.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

Art Unit: 1637

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305)-7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. Tung*
May 22, 2005

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/24/05